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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,675	04/13/2001	Thomas Weimer	06478.1454-00	2127

22852 7590 05/27/2003

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/27/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	09/833,675		WEIMER, THOMAS	
	Examiner		Art Unit	
	Cheyne D Ly		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 10-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
        1. ☐ Certified copies of the priority documents have been received.  
        2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Applicant's election with traversal of Group I, claims 10-25, Hepatitis C Viral genome, and polymerase chain reaction, in Paper No.8, filed April 25, 2003, is acknowledged.
2. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on claims of Groups I and II together. This is not found persuasive because Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the process for identifying one or more heterologous oligonucleotide sequences for use in amplifying a target nucleic acid sequence was used to identify a reagent set which includes at least one of the oligonucleotide primers selected from SEQ ID NOs. listed in claim 27, alternatively, the said process may be used to identify oligonucleotide primers not listed in this instant application. This lack of overlapping searches documents the undue search burden if they were search together.
3. Specific to the sequence and species election requirements, the traversal is on the ground(s) that it would not be unduly burdensome to perform a search on the claimed invention without electing specific SEQ ID or an amplification method. Further, it is acknowledged that claims 10- 25 are generic to the elected claimed invention. However, the recitation of these specific SEQ IDs in claim 12, and amplification methods in claim 24 has made it necessary to restrict the claimed invention to a specific sequence and amplification method in order to achieve a thorough examination of this instant application without undue search burden. Otherwise, the

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lack of overlapping searches of SEQ Ids 1-9 and various amplification methods would cause an undue search burden if they were search together.

4. The requirement is still deemed proper and is therefore made FINAL.
5. Claims 10-25, Hepatitis C Viral genome, and polymerase chain reaction are examined on the merits.

#### **PRIORITY**

6. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Germany. It is noted, however, that the certified foreign priority documents are not in English. Therefore, the priority cannot be granted without certified copies, and, certified translations if the documents are in a foreign language.

#### **CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 10-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Specific to claims 10, line 5; 13-16, line 1; and 20, line 4, the phrase “ mutually overlapping” causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a nucleic acid “mutually overlaps” with another (sequences having identical polynucleotide sequences or complementary of sense with anti-sense sequences). Also, are overlapping DNA molecules single or double stranded? Applicant can resolve this issue by particularly pointing out the criteria that is used to determine that a series of DNA molecules are

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overlapping. Clarification of the metes and bounds of the instant claims is required. Claims 11, 12, 17-19, 21-25 are rejected due to being directly or indirectly dependent from claim 10 or 20.

10. Specific to claim 21, the term "universal" causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a specific base is "universal" (a base can be found any where in the universe or applicable to all purposes). Applicant can resolve this issue by particularly pointing out the criteria that is used to determine that a specific base is "universal". Clarification of the metes and bounds of the instant claims is required.

11. Specific to claim 22, the term "completely" causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a nucleic acid is "completely" hybridize with the target nucleic acid (degree to which a nucleic acid anneals to a target nucleic acid, or all of a specific sequence length of a nucleic acid anneals to a portion or all of the sequence length of a target nucleic acid). Applicant can resolve this issue by particularly pointing out the criteria that is used to determine that a specific hybridization is complete.

Clarification of the metes and bounds of the instant claims is required.

#### **CLAIM REJECTIONS - 35 USC § 102**

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 10-18 and 20-25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Neri et al. (US 6,194,149 B1).

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14. Neri et al. discloses a method of identifying oligonucleotides for performing target-dependent reactions. The method of Neri et al. comprises selecting the target nucleic acid sequence, generating overlapping fragments to a conserved region (column 46, lines 50-60) and determining the similarity of the fragments by an alignment (Figures 18 a-d), as in claims 10 and 11.

15. Figure 18 a discloses an oligonucleotide from 70 to 263 of HCV 1a with a nucleotide sequence CCC that is identical to the oligonucleotide sequence of SEQ ID NO. 1 of this instant application, as in claims 12-17.

16. A record reference library of genetic fingerprints comprising nucleic acids is generated with the method of Neri et al. (column 12, lines 36-48), as in claim 18.

17. Oligonucleotide probes comprise of universal bases (column 10, lines 20-27) and which may include inosine (column 26, lines 11-18). Further, the probes having mismatches are used for more sensitive detection method (column 50, example 1), as claims 20 and 21.

18. Probes are used for hybridization analysis in HCV genotyping (column 53, Example 3), as in claim 22.

19. The primers are employed for polymerase chain reactions (PCR) (column 54, lines 61-67 to column 55, lines 1-15), as in claims 23-25.

**Claim Rejections - 35 USC § 103**

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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21. Claims 10-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al. Neri et al (US 6,194,149 B1) taken with Tureci et al. (US 6,214,983 B1).

22. Neri et al. discloses the limitations, which clearly anticipate claims 10-18 and 20-25 as cited above.

23. However, Neri et al. does not disclose that the oligonucleotide sequences are identified in a DNA sequence library, as in claim 19.

24. Tureci et al. discloses a method comprise an electronic search of the GenBank database to identify know nucleic acid molecules and the results of the said search was used to generate primers (column 4, lines 9-27), as in claim 19.

25. An artisan of ordinary skill in the at the time of the instant invention would have been motivated to partake the concept emphasized by Neri et al. for a method of identifying oligonucleotides for performing target-dependent reactions and to improve on the said method by performing GenBank searches to identified oligonucleotides as taught by Tureci et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of identifying oligonucleotides for performing target-dependent reactions as taught by Neri et al. and performing GenBank searches to identified oligonucleotides as taught by Tureci et al.

#### **CONCLUSION**

26. NO CLAIM IS ALLOWED.

27. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157

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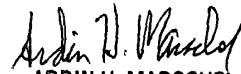
OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

30. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
5/22/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER